

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

In re Namenda Direct Purchaser Antitrust
Litigation

THIS DOCUMENT RELATES TO:
All Direct Purchaser Actions

Case No. 1:15-cv-07488-CM (RL)

FILED UNDER SEAL

**MEMORANDUM OF LAW IN SUPPORT OF FOREST'S MOTION TO EXCLUDE
OPINIONS AND PROPOSED TESTIMONY OF GEORGE W. JOHNSTON, ESQ.**

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I. INTRODUCTION

The Court should exclude Plaintiffs' claimed expert witness George Johnston under Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Mr. Johnston is an attorney whose reports are essentially legal briefs arguing Plaintiffs' position regarding the patent case underlying this antitrust action. He discusses patent law at-length, summarizes the evidence and opinions of the scientific experts in the underlying case, and reaches factual and legal conclusions regarding the merits of the parties' claims and defenses. He is admittedly not a technical expert, yet he plans to offer opinions regarding patent infringement and validity; those opinions are improper under settled law. He claims to provide the perspective of an experienced pharmaceutical patent attorney (although he has no first-hand trial experience), but his qualifications do not justify invading the provinces of the Court to interpret the law or of the jury to apply the law to the facts. And his opinions do just that: he testified that part of his methodology was to "set forth the law and apply the law to the facts," i.e., the very work of the judge and jury. Furthermore, Mr. Johnston's opinions raise issues that were completely absent from patent defendant Mylan's proposed trial presentation. Such revisionist history is irrelevant to this case. Permitting Mr. Johnston to testify at trial would be tantamount to permitting a party to argue its case to the jury from the witness stand, using a hired expert attorney as its mouthpiece. Because that approach is unquestionably impermissible, Mr. Johnston should be excluded.

II. BACKGROUND

Mr. Johnston served an opening report on September 15, 2017. Declaration of Michael E. Hamburger, dated November 17, 2017 ("Hamburger Decl.") Exhibit 12 ("Johnston Rep."). Mr. Johnston is a patent attorney who spent much of his career as in-house counsel for

pharmaceutical company Hoffman-La Roche Inc. (“Roche”). *Id.* ¶¶ 2-3. In describing his expertise, Mr. Johnston emphasizes his knowledge of patent law and its application in the pharmaceutical industry. He states in his report that he is “an attorney, . . . [having] particular knowledge of patent law . . . [as he] spent [his] entire practice working in that area of the law.” *Id.* ¶ 73. He also states that he gained experience “advis[ing] senior management on the likelihood that Roche would prevail in potential and actual patent litigations.” *Id.* ¶ 5.

Mr. Johnston’s opening report includes a 70-page “Evaluation of the Merits of the ‘703 Patent Claims” section. *Id.* ¶¶ 110-401. In that section, he opines on the hypothetical outcome of the patent litigation between Forest and Mylan regarding the ‘703 patent. *See generally id.* He discusses the law of patent infringement and validity at length, reviews the evidence and expert opinions that Forest and Mylan might have offered at trial, and opines on whether each claim or defense was likely to prevail by assigning each a numerical likelihood. He attached to his report a 21-page discussion of the law of patent infringement and validity, which he described as “relevant to the statements and opinions contained in this report.” *Id.* ¶ 73 & Exhibit M (“Legal Understanding and Standard”).

Mr. Johnston’s “Evaluation of the Merits” reads like a legal brief or a judicial opinion summarizing the evidence and drawing legal conclusions; he even referred to his reports as his “briefs” several times during his deposition (before correcting himself). Hamburger Decl., Ex. 31 (Johnston Dep.) at 145:2-3, 176:8-16, 222:23-25, 235:17. He addresses five substantive issues from the patent litigation in detail: (1) anticipation under 35 U.S.C. § 102 (Hamburger Decl., Ex. 12 (Johnston Rep.) ¶¶ 125-59); (2) obviousness under 35 U.S.C. § 103 (*id.* ¶¶ 160-87); (3) enablement under 35 U.S.C. § 112 (*id.* ¶¶ 188-290); (4) the Patent Term Extension Forest received for the ‘703 patent under 35 U.S.C. § 156 (*id.* ¶¶ 291-353); and (5) infringement of the

‘703 patent by Mylan (*id.* ¶¶ 354-392). He concludes that: (1) “Mylan met its burden” of proof on its §§ 102, 112, and 156 defenses; (2) Mylan presented a *prima facie* case of obviousness under § 103 that would have been difficult for Forest to overcome; and (3) “Forest and Merz did not meet their burden” of proof on infringement. *Id.* ¶ 395 (“Summary Table”). He provides these opinions from the perspective of “what a reasonable patent attorney would perceive as the likelihood of success [on the parties’ claims and defenses] at the time of settlement.” Hamburger Decl., Ex. 31 (Johnston Dep.) at 12:7-13:3.

III. ARGUMENT

A. Mr. Johnston Does Not Have The Technical Expertise Required To Opine On Patent Infringement And Validity

“[I]t is an abuse of discretion to permit a witness to testify as an expert on the issues of noninfringement or invalidity unless that witness is qualified as an expert in the pertinent art.” *Sundance, Inc. v. Demonte Fabricating Ltd.*, 550 F.3d 1356, 1363 (Fed. Cir. 2008); *see also Williamson v. Verizon Communs. Inc.*, No. 11-CV-4948, 2012 U.S. Dist. LEXIS 161354 at *5 (S.D.N.Y. Nov. 7, 2012) (finding that in a patent case, “[t]estimony proffered by a witness lacking the relevant technical expertise fails the standard of admissibility under Fed. R. Evid. 702.”) (quoting *Sundance*, 550 F.3d at 1363). This is because “issues of infringement or validity . . . are analyzed in great part from the perspective of a person of ordinary skill in the art, and testimony explaining the technical evidence from that perspective may be of great utility to the factfinder.” *Sundance*, 550 F.3d at 1361. A patent attorney who does not have relevant technical expertise is not qualified to provide that perspective and therefore his or her testimony would “serve[] only to cause mischief and confuse the factfinder.” *Id.* at 1362.

Mr. Johnston repeatedly testified that he is not a technical expert or even a person of ordinary skill in the art. *E.g.*, Hamburger Decl., Ex. 31 (Johnston Dep.) at 170:6-8 (“Let me

make clear, I do not consider myself as a technical expert, particularly in this matter.”), 172:2-21 (agreeing that he is “not a technical expert in the field of the ‘703 patent,” is “not a person of ordinary skill in the art to which the ‘703 patent pertains,” and does “not have the expertise that [the technical] experts [in the ‘703 patent litigation] possessed”); *see also* Hamburger Decl., Ex. 12 (Johnston Rep.) ¶ 15, n.2 (“I do not consider myself as a technical expert or a person of ordinary skill in the field of the ‘703 patent”). He is therefore not qualified to opine on the issues of infringement and validity he raises in his report. *Sundance*, 550 F.3d at 1361; *Williamson*, 2012 U.S. Dist. LEXIS 161354 at *5. Indeed, he agrees that “if the ‘703 patent litigation had gone to trial it would have been *technical experts* that testified on the issues of infringement [and validity].” Hamburger Decl., Ex. 31 (Johnston Dep.) at 174:13-23 (emphasis added). In this case, both sides have offered opinions from technical experts to address the questions of patent infringement and validity that Mr. Johnston addresses from his perspective as a lawyer. It is those technical experts’ opinions that may help the jury assess the merits of the patent case, not Mr. Johnston’s.

In response to Mr. Johnston, Forest served an expert report from Roderick McKelvie. Mr. McKelvie is a former district court judge from the District of Delaware who presided over dozens of patent trials while on the bench and, after returning to private practice, regularly represented clients in connection with patent litigation. Mr. McKelvie “disagree[s] with Mr. Johnston’s opinion that Mylan was likely to prevail at trial,” in view of the “competing and contradictory theories of its case” Mylan was planning to offer, Forest’s “substantial evidence of infringement,” [REDACTED]

[REDACTED] . . . [making it] highly unlikely that Mylan would

have been able to prove invalidity at trial.” Hamburger Decl., Ex. 13 ¶ 16 (Expert Report of Roderick McKelvie, dated Oct. 9, 2017) (“McKelvie Rep.”). But Forest will withdraw all such opinions from Mr. McKelvie if the Court grants this motion to exclude Mr. Johnston from testifying at trial.

B. Mr. Johnston’s Opinions On The Law And Legal Conclusions About The Merits Of The Patent Case Are Impermissible

“It is not for witnesses to instruct the jury as to applicable principles of law, but for the judge.” *Marx & Co. v. Diners’ Club, Inc.*, 550 F.2d 505, 509-10 (2d Cir. 1977). Accordingly, any testimony that “is designed to instruct the jury on the applicable law is not admissible,” as that responsibility “lies with the exclusive province of the court.” *Bausch & Lomb, Inc. v. Alcon Labs., Inc.*, 79 F. Supp. 2d 252, 255 (W.D.N.Y. Jan. 5, 2000) (citing *United States v. Scop*, 846 F.2d 135, 140 (2d Cir. 1988)). Likewise, experts may not offer legal conclusions in the form of opinions. *Hygh v. Jacobs*, 961 F.2d 359, 363 (2d Cir. 1992) (“This circuit is in accord with other circuits¹ in requiring exclusion of expert testimony that expresses a legal conclusion”); *United States v. Bilzerian*, 926 F.2d 1285, 1294 (2d Cir. 1991) (expert testimony cannot “usurp either the role of the trial judge in instructing the jury as to the applicable law or the role of the jury in applying that law to the facts before it.”); *United States v. Scop*, 846 F.2d 135, 139 (2d Cir. 1988) (“Rule 704 was not intended to allow experts to offer opinions embodying legal conclusions.”).

Mr. Johnston discusses patent law at length throughout the “Evaluation of the Merits” section of his expert report and in his Exhibit M, an additional 21-page summary of patent laws

¹ See also *Jimenez v. City of Chicago*, 732 F.3d 710, 721 (7th Cir. 2013) (“As a general rule . . . an expert may not offer legal opinions.”); *Elsayed Mukhtar v. Cal. State Univ., Hayward*, 299 F.3d 1053, 1065 n.10 (9th Cir. 2002) (An expert cannot “give an opinion as to [his] legal conclusion, i.e., an opinion on an ultimate issue of law.”); *Torres v. County of Oakland*, 758 F.2d 147, 150 (6th Cir. 1985) (rejecting expert testimony that was “couched as a legal opinion”).

that he references throughout his report. *E.g.*, Hamburger Decl., Ex. 12 (Johnston Rep.) ¶¶ 125, 126, n.57, 153 (discussing and applying law of anticipation); ¶¶ 171, 180 (discussing and applying law of obviousness); ¶¶ 188-91, 230-34, 244, 254, 258 & n.106, 279-86 (discussing and applying law of enablement); ¶¶ 295-344 (statutory interpretation and legislative history for PTE); ¶¶ 355, 356-376, 378 (discussing and applying law of infringement); Exhibit M (additional patent law summary). He did not dispute this in his deposition. Hamburger Decl., Ex. 31 (Johnston Dep.) at 176:23-177:1. Beyond merely stating his view of the law, he admitted that part of his methodology in preparing his report was to “set forth the law *and apply the law to the facts.*” *Id.* at 216:17-20 (emphasis added). This approach is the very essence of impermissible expert opinion from an attorney, as it invades the province of both Judge and jury. *Marx & Co.*, 550 F.2d at 509-10; *Hygh*, 961 F.2d at 363.

For example, in his discussion of enablement, Mr. Johnston states: “Two cases involving the enablement of method of treatment claims are instructive: *Rasmusson, v. SmithKline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005) and *In re ‘318 Patent Infringement Litigation*, 578 F. Supp. 2d 711 (D. Del. 2008), *aff’d* 583 F.3d 1317 (Fed. Cir. 2009).” Hamburger Decl., Ex. 12 (Johnston Rep.) ¶ 230. He then discusses those two cases in detail over the next two pages of his report, analogizes their facts to those at-bar, and concludes: “[u]nder those circumstances and the holdings of *Rasmusson* and *In re ‘318 Patent Infringement Litigation*, in my opinion the ‘703 patent did not enable one skilled in the art how to use the method of treatment claims to treat Alzheimer’s disease using memantine.” *Id.* ¶¶ 231-37. Thus, Mr. Johnston has reached a legal conclusion based on his evaluation and application of case law to the facts of the case. *See id.* at ¶ 191 (admitting that “[e]nablement is a question of law”). This

opinion is impermissible from an expert. *Marx & Co.*, 550 F.2d at 509-10; *Hygh*, 961 F.2d at 363.

Mr. Johnston takes the same approach to the other claims and defenses at-issue in the patent case, frequently in terms of whether each party had met its burden of proof. On anticipation under 35 U.S.C. 102, he opined: “[i]n my opinion, a reasonable and competent patent attorney would have realized that . . . Mylan had met its burden and could prevail with regard to invalidating the claims . . . under 35 U.S.C. 102.” Hamburger Decl., Ex. 12 (Johnston Rep.) ¶ 158. On obviousness under 35 U.S.C. 103, he opined: “Mylan presented a strong showing that the claimed subject matter was *prima facie* obvious” and “it would be difficult for Forest . . . to overcome this *prima facie* case.” *Id.* ¶¶ 183-84. On infringement, he opined: “In my opinion and for the above reasons, Forest . . . would not have proved that Mylan infringed independent claims 1, 14, and 17.” *Id.* ¶ 377. And in addition to the enablement analysis described above, Mr. Johnston conducted another enablement analysis pursuant to *In re Gardner*, 427 F.2d 786 (C.C.P.A. 1970), which he described as a “seminal case” on enablement, concluding: “As in *Gardner* and in my opinion, the ‘703 method of treatment claims are invalid because they are not enabled by the specification under 35 U.S.C. 112, ¶ 1.” *Id.* ¶ 279, 286.

This kind of legal analysis pervades Mr. Johnston’s report. All of his opinions on the merits of the ‘703 patent litigation (i.e., his section entitled “Evaluation of the Merits”) fundamentally depend on his assessment of the law and application of the law to the facts as he sees them, both impermissible analyses for an expert. Mr. Johnston agreed that it would be improper for Plaintiffs’ counsel to take the witness stand and offer those same opinions, but claimed that he could do so himself because “I have more expertise to answer the questions that have been presented to me,” owing to his experience as in-house patent counsel for a

pharmaceutical company. *See* Hamburger Decl., Ex. 31 (Johnston Dep.) at 218:21-219:18, 220:15-222:14. But even the utmost legal qualifications do not justify permitting an attorney to advocate from the witness stand, usurping the Judge's role in determining the law and the jury's role in applying that law to the facts. *See Inventio AG v. Otis Elevator Co.*, No. 06-cv-5377, 2011 U.S. Dist. LEXIS 88965 at *5-6 (S.D.N.Y. Jun. 23, 2011) (McMahon, J.) (finding attorney testimony explaining the law to a jury to be impermissible "no matter their credentials").

Mr. Johnston concedes that, if he could not opine on the law as he sees it, his opinions would "be very hard to understand." Hamburger Decl., Ex. 31 (Johnston Dep.) at 215:5-13. Accordingly, simply excluding *portions* of Mr. Johnston's opinions on the merits of the '703 patent litigation (*i.e.*, his section entitled "Evaluation of the Merits") is unrealistic. What would remain for him to opine on — if anything — would be confusing, if not impossible, for the jury to follow. *See* Fed. R. Evid. 403 (authorizing exclusion of evidence that may confuse the issues or mislead the jury). The Court should therefore exclude all testimony from Mr. Johnston on the merits of the '703 patent litigation.

C. Mr. Johnston Cannot Opine On Issues That Forest And Mylan Did Not Intend To Raise At Trial

An expert's opinion is admissible only if it "will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702; *Daubert*, 509 U.S. at 589-93. Here, the factual question for the jury is whether, if Forest and Mylan had not reached their settlement, Mylan would have somehow prevailed at trial and launched its generic product earlier than it did under the settlement. The relevant analysis therefore must focus on the issues in the '703 patent case as Forest and Mylan were prepared to try them. The best evidence of what the parties' trial would have looked like is their comprehensive, 301-page pretrial order, which includes 187 pages of proposed findings of fact and conclusions of law from both sides. *See* Hamburger

Decl., Ex. 40 (Mylan's Proposed Findings of Fact and Conclusions of Law). But many of Mr. Johnston's opinions raise issues and legal arguments that were either undeveloped or completely absent from the parties' pretrial order, making them irrelevant:

- [REDACTED]

- [REDACTED]

- [REDACTED]

- [REDACTED]

- [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Indeed, Mr. Johnston appears to disregard the parties' pretrial order entirely when it suits his opinions, claiming that "a pretrial order is not all-inclusive," and because the judge presiding over the patent case had not signed it, "I assume [the parties] could have modified it."

Hamburger Decl., Ex. 31 (Johnston Dep.) at 61:15-62:5. When asked whether Mylan was obligated to mention a genus-species theory of anticipation in its proposed conclusions of law if it was going to pursue that specific theory at trial, Mr. Johnston opined: “I don’t think it had the obligation to do that with any more specific detail than it did.” *Id.* at 63:24-64:6. Whatever obligations Mylan had to articulate its theories, the parties’ pretrial order is the best evidence we have of what issues they planned to pursue at trial. Mr. Johnston’s new theories are simply irrelevant to the issue in this case and therefore should be excluded.

D. Mr. Johnston’s Opinions That Most Patentees Lose At Trial And That The ‘703 Patent Was A “Third Tier Patent” Are Inadmissible

In addition to his improper opinions on the merits of the patent case, Mr. Johnston offers several other reasons why he thinks Forest was likely to lose at trial. First, he claims that experienced patent lawyers understand what lay jurors do not: it may seem significant that a patent is a document issued by a qualified government agency (the PTO) after examination proceedings, but in reality, patents usually fail in litigation. Hamburger Decl., Ex. 12 (Johnston Rep.) ¶¶ 76-86. Second, he cites statistical analyses in support of his blanket claim that patents usually do not hold up in litigation, again implying that the ‘703 patent was likely to fail. *Id.* at ¶¶ 87-109. Third, he classifies pharmaceutical patents as first, second, or third-tier and puts the ‘703 patent in the third (and allegedly weakest) group, suggesting it was inherently vulnerable. *Id.* at ¶¶ 112-120. All of these opinions are impermissible because they seek to undermine the statutory presumption of patent validity, which indisputably applied to the ‘703 patent, and which could be overturned only by clear and convincing evidence. *See* 35 U.S.C. § 282(a) (“A patent shall be presumed valid.”); *Bausch & Lomb*, 79 F. Supp. 2d at 255 (excluding testimony offered simply to “undermine the presumption of validity under 35 U.S.C. § 282 by inviting the jury to speculate about possible defects, errors, or omissions in the application process that led to

the issuance of the patent-in-suit”); *see also Icon-IP Pty Ltd. v. Specialized Bicycle Components, Inc.*, 87 F. Supp. 3d 928, 947 (N.D. Cal. 2015) (disallowing “generalized testimony about quotas, time pressures, or the problems examiners generally face in completing their work at the PTO” from a former Patent Office examiner offered to undermine presumption of validity).

Furthermore, Mr. Johnston’s classification of the ‘703 patent as “third tier” is simply another improper legal conclusion regarding its overall strength — one that is unfairly prejudicial, as it directly undermines the statutory presumption of validity. The Court should not permit Mr. Johnston, who admittedly lacks the technical expertise to address the ‘703 patent’s validity from the required perspective of a person of ordinary skill, to disparage the ‘703 patent’s invention based on his purported experience with other patents allegedly claiming similar inventions.

IV. CONCLUSION

For the forgoing reasons, the Court should exclude Mr. Johnston from testifying at trial in this case.

Plaintiffs served an expert report from another attorney, Professor John R. Thomas, on November 14, 2017, pursuant to the Court’s August 21, 2017 Order authorizing service of an additional expert report after the close of expert discovery. *See* Dkt 355 at 16 (giving Plaintiffs sixty additional days to produce a new expert report). Forest’s review of Mr. Thomas’s opinions is not yet complete and he has not yet been deposed, but he appears to be a professor of patent law who opines on the Hatch-Waxman Act and applies the Act’s provisions to the approval of several memantine ANDAs. Mr. Thomas’s opinions appear to be objectionable for many of the

same reasons proved in this motion. Forest reserves the right to move to exclude Mr. Thomas's testimony once discovery on his recently provided opinions is complete.

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